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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,501	03/03/2000	Mark D Erion	030727.0013.CIP1	7608

36183 7590 06/16/2003

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EXAMINER
MCKENZIE, THOMAS C

ART UNIT	PAPER NUMBER
1624	22

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/518,501	ERION ET AL.	
	Examiner	Art Unit	
	Thomas McKenzie Ph.D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,20-46,48-57,150-153,155-157,165,166 and 171-173* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,20-46,48-57,150-153,155-157,165,166 and 171-173* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. This action is in response to an RCE and amendments filed on 4/17/03. There are sixty-seven claims pending and sixty-seven are under consideration. Claims 1-16, 17-46, 48-57, 165, and 171-173 are compound claims. Claims 150-153, 155-157 are method of preparation claims. Applicants have amended claims 31, 35, 173, and the specification. These amendments correct some minor typos and introduce no new matter. This is the third action on the merits. The application concerns some cyclic phosphate amides and preparations thereof. This is the first action on the merits.

2. Applicants enquired about the rejections made to claim 154 in the final rejection. Applicants are correct that claim 154 had been canceled. Although the Examiner did not indicate that the claim was pending in his preliminary remarks, he mistakenly included in the blanket rejections to the method of preparation claims. The Examiner regrets the error.

Continued Examination Under 37 CFR 1.114

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous

Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/17/03 has been entered.

Response to Amendment

4. The declaration under 37 CFR 1.132 filed 1/22/03 by Dr. Mark Erion is insufficient to overcome the rejection of claims 1-3, 7, 9-18, 20-46, 48-53, 150-153, 155-157, 165, 166, and 171-173 based upon lack of enablement and indefiniteness as set forth in the last Office action because: Dr. Erion points to page 15 presumably lines 7-23 as defining the term. The concept of prodrug is not in dispute, what is uncertain is the structures of these claimed compounds. Dr. Erion asserts without evidence that preparation of prodrugs, no matter what their structure, is now routine experimentation. Firstly, Rule 132 declarations are a mechanism to introduce evidence and must set forth facts, not merely conclusions, *In re Pike* 84 USPQ 235. Allegations are not probative, *In re Brandstadter* 179 USPQ 286, *In re Knowlton* 183 USPQ 33. Secondly, Applicants' specification says the opposite. In lines 7-27, page 27 they state that acyloxyalkyl esters are the only common prodrugs of hydroxyl containing drugs. They then state that even these esters are not very satisfactory and the act of placing such an ester upon a hydroxyl group does not guarantee that the resulting ester will be a prodrug.

Claim Rejections - 35 USC § 112

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 1-3, 7, 9, 11-18, 20-46, 48-53, 56, 150-153, 155-157, 165, 166, and 171-173 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase in lines 20-21, page 2, claim 1, "M is selected from ... is a biologically active agents but is not an FBPase inhibitor" is indefinite. What is the structure of radical M? What do Applicants intend by "biologically active agent? How active and active as what? The phrase also occurs in claims 150; 166, `171, 172, and 173.

The Examiner suggests using chemical formulas to define the structure of the claimed "M" radical.

6. Claims 1-3, 7, 9-18, 20-46, 48-53, 150-153, 155-157, 165, 166, and 171-173 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase in lines 18-19, page 13, claim 1, "M is selected from ... is a biologically active agents but is not an FBPase inhibitor" lacks written description. Applicants' claims are drawn to any radical derived from a molecule with a certain functional group and with a general

biological property. What are the structures of these radicals? Structural formulas, names, or both can accurately describe organic compounds, which are the subject matter of claims 1-3, 7, 9-18, 20-46, 48-53, 150-153, 155-157, 165, 166, and 171-173. Attempting to define means by function is not proper when the means can be clearly expressed in terms that are more precise. Applicants' dependant claims, listing the specific diseases treated by drugs containing radical M, do not clarify what chemical radicals are intended here.

The radical M is an essential feature. The fact the dependant claims specify that radical M can be a purine or pyrimidine ring make clear that M is the heterocyclic core of formula I. The skilled medicinal chemist would not understand from the phrase in question, what radicals M were intended. Applicants' exclusions of alkyl amines, which are not biologically active, from the list of claimed M groups means that they also do not understand the phrase. According to the MPEP § 2163 I. "[a]n applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, **structures** [emphasis added], figures, diagrams, and **formulas** [emphasis added], that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an

actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or **structural chemical formulas** [emphasis added], that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). "Compliance with the written description requirement is essentially a fact-based inquiry that will necessarily vary depending on the nature of the invention claimed." *Enzo Biochem*, 296 F.3d at 1324, 63 USPQ2d at 1613." Applicants' limited structural information is not sufficient to distinguish their compounds.

7. Claims 1-3, 7, 9-18, 20-46, 48-53, 150-153, 155-157, 165, 166, and 171-173 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making the compounds of dependant claims 4-6, 8, 10, 54, 55, and 57, does not reasonably provide enablement for making all compounds where M is defined in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

make the invention commensurate in scope with these claims. "The factors to be considered [in making an enablement rejection] have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims", *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. a) Preparing any particular compound would first require ascertaining the structure of the M radical, devising a synthesis of the substance, and performing the required synthesis in the laboratory. This is an open-ended and potentially inconclusive degree of experimentation. b) The direction concerning synthesis is found in the passage spanning line 6, page 89 to line 32, page 98. This passage describes general procedures to be used with M radicals possessing specific functional groups, not every potential M radical. c) That are twenty-one working examples of synthesis of a compound of formula (I). This is found in the passage spanning line 28, page 103 to line 22, page 107 as well as line 12, page 111 to line 11, page 114. d) The nature of the invention is chemical synthesis, which involves chemical reactions. e) The state of the art is instructions to a pharmacologist or physician to search for some particular drug hardly constitute

directions to the average BS organic chemist of how to make these compounds attached to Applicants cyclic phosphonamide array. f) The artisan using Applicants invention to prepare the claimed compounds would be a process chemist or pilot plant operator with a BS degree in chemistry and several years of experience. g) Chemical reactions are well-known to be unpredictable, *In re Marzocchi*, 169 USPQ 367, *In re Fisher*, 166 USPQ 18. h) The breadth of the claims includes all of the unknown number compounds of formula I.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

The arguments concerning the three rejections concerning the structure of M will be considered together. Applicants argue that the phrase "biologically active agent" is well understood and point to page 15 as indicative of the therapeutic agents they intend. This is not persuasive because the issue is not that of the meaning of "biologically active agent" but rather Applicants complete claim

limitation concerning the attachment of that agent to four different phosphorus species listed in line 20, page 2. The search done previously by the Examiner was for documents containing the phrase "biologically active agent" and near by one of the words "group", "attached", or "PO_3^{-2}". Applicants apparently searched only for the phrase "biologically active agent". Must the molecule containing M attached to any of these four phosphorus species be currently recognized as biologically active? Or does the limitation include biologically active molecules M-H not containing phosphorus but which retain biologically activity when any hydrogen atom in the substance is replaced by a phosphorus species? Could it mean that biologically inactive molecules M-H, which become biologically active when converted into Applicants' formula I are intended?

Lines 22-23, page 15 define "biologically active compound" not biologically active agent and uses open language "for example". The passage spanning pages 21-22 but basically defines the phrase biologically active agent in terms of itself. The passage spanning pages 21-22 fails to clarify if only the therapeutic agents mentioned on page 15 are intended or if poisons, like the commercial herbicide Ethephon, which have no therapeutic effect, and biochemical intermediates, like ATP, which are active in living things but have no therapeutic effect are meant.

Applicants' remarks state that therapeutically used compounds are the only ones intended but that is not a claim limitation.

8. Claims 1-18, 20-46, 48-57, 150-153, 155-157, 165, and 171-173 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 25, page 13 claim 1, Applicants claim "prodrug". The word "prodrug" is indefinite. The issue on second paragraph is whether the structures of the claimed compounds are clearly defined. Applicants' "prodrugs" are molecules whose structure lie outside the subject matter of formula I, but upon metabolism in the body are converted to active compounds falling within the structural scope of formula I. The claim describes the function intended but provides no specific structural guidance to what constitutes a "prodrug". The word also occurs in claims 150, 171, 172, and 173.

The Examiner suggests deleting the word prodrug.

9. Claims 1-3, 7, 9-18, 20-46, 48-53, 150-153, 155-157, 165, 166, and 171-173 are newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The word

"prodrug" in line 25, page 13, claim 1, lacks written description. Applicants' claims are drawn to any derivative of the compounds of formula I with a specific biological property. What are the structures of these prodrugs? Structural formulas, names, or both can accurately describe organic compounds, which are the subject matter of claims 1-3, 7, 9-18, 20-46, 48-53, 150-153, 155-157, 165, 166, and 171-173. The issue was discussed above in the paragraph concerning written description of radical "M".

10. Claims 1-3, 7, 9-18, 20-46, 48-53, 150-153, 155-157, 165, 166, and 171-173 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making the salts of the compounds of formula I, does not reasonably provide enablement for making prodrugs of those compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Directions to a team of pharmacologist, medicinal chemists, and pharmacokinetics experts of how to search for Applicants prodrugs hardly constitute direction to the process chemist of how to make these claimed compounds.

11. Applicants use prodrug in two different ways. They assert that the compounds of formula I are themselves prodrugs. That is not the present issue but rather that of prodrugs which produce compounds of formula I.

The factors to be considered in making an enablement rejection have been summarized above. a) Finding a prodrug is an empirical exercise. Predicting if a certain ester of a claimed alcohol, for example, is in fact a prodrug, that produces the active compound metabolically, in man, at a therapeutic concentration and at a useful rate is filled with experimental uncertainty. Although attempts have been made to predict drug metabolism *de novo*, this is still an experimental science. For a compound to be a prodrug, it must meet three tests. It must itself be biologically inactive. It must be metabolized to a second substance in a human at a rate and to an extent to produce that second substance at a physiologically meaningful concentration. Thirdly, that second substance must be biologically active. Determining whether a particular compound meets these three criteria in a clinical trial setting requires a large degree of experimentation.

b) There is extensive discussion of the concept of prodrug and how to search for and prepare compounds of formula I that are themselves prodrugs. The direction concerning making the prodrugs, which liberate the compounds of formula, I is found in lines 13-16, page 30. This passage just states Applicants

intent to do so. c) There is no working example of a prodrug which produces a compound of formula I. The biological data in the passage spanning line 10, page 115 to line 26, page 126 do not demonstrate that even any of the compounds of formula I are themselves prodrugs. The only *in vivo* experiments, Examples O-S appear to be prophetic and not working examples. d) The nature of the invention is clinical use of compounds and the pharmacokinetic behavior of substances in the human body. e) The state of the prodrug art is summarized by Wolff (Medicinal Chemistry). The table on the left side of page 976 outlines the research program to be undertaken to find a prodrug. The second paragraph in section 10 and the paragraph spanning pages 976-977 indicate the low expectation of success. In that paragraph the difficulties of extrapolating between species are further developed. Since, the prodrug concept is a pharmacokinetic issue, the lack of any standard pharmacokinetic protocol discussed in the last sentence of this paragraph is particularly relevant. Banker (Modern Pharmaceutics) in the first sentence, third paragraph on page 596 states that "extensive development must be undertaken" to find a prodrug. f) Wolff (Medicinal Chemistry) in the last paragraph on page 975 describes the artisans making Applicants' prodrugs as a collaborative team of synthetic pharmaceutical chemists and metabolism experts. g) The lack of predictability in finding prodrugs was discussed above. h) The breadth of the

claims includes all of the hundreds of thousands of compounds of formula of claim 136 as well as the presently unknown list potential prodrug derivatives embraced by claim 136.

Thus, undue experimentation will be required to determine if any particular derivative is, in fact, a prodrug.

The arguments concerning the three rejections concerning prodrug will be considered together. Applicants make four arguments concerning indefiniteness. Firstly, they rely upon the declaration discussed above. Secondly, they argue that no standard recipe for making prodrugs is required to make the term definite. Thirdly, the word is used in many other patents. Fourthly, there is nothing inherently wrong with functional language. This is not persuasive. Firstly, the declaration is discussed above. Secondly, the Examiner, as an ex-chemist, prefers the word procedure or protocol to recipe, but agrees that is an accurate description of the factual situation. Namely that the concept of prodrug is widely understood but no general and reliable procedure exists for making them. As such, a claim to prodrug is akin to a product by process claim but the process is left undefined. Applicants are invited to cite a case law in support of their assertion that no recipe is required for such a claim to be definite. Thirdly, The indefiniteness remains despite what was allowed in another case. The U.S. Court of Customs and Patent

Appeals wrote *In re Giolito* 188 USPQ 645: "We reject appellants' argument that the instant claims are allowable because similar claims have been allowed in a patent. It is immaterial whether similar claims have been allowed to others. See *In re Margaroli,* 50 CCPA 1400, 318 F.2d 348, 138 USPQ 158 (1963); *In re Wright*, 45 CCPA 1005, 256 F.2d 583, 118 USPQ 287 (1958); *In re Launder*, 41 CCPA 887, 212 F.2d 603, 101 USPQ 391 (1954)".

Fourthly, the Examiner agrees that functional language is proper according to the MPEP §2173.05(g) when "it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used" what was intended The word prodrug fails to allow the skilled medicinal chemist to envisage what derivatives are being claimed as evidenced by Applicants argument that no standard recipe exists. The U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences held in *Ex parte Pulvari* 157 USPQ 169 that "a material defined, as here, solely in terms of what it can do, of a property thereof or of the scientific principle that underlies that property ... does [not] particularly point out, as required by 35 U.S.C. 112, appellant's disclosed invention".

Concerning the enablement rejection, Applicants assert that the Examiner had found preparation of prodrugs standard in the art. They make three arguments traversing the rejection. Firstly, that the experimentation to make such compounds

is routine. Secondly that the declaration of Dr Erion provides the support for their claims. Thirdly, that the references cited by the Examiner are not persuasive. The Examiner did not find that preparation of prodrugs to be standard in the art. Any inference that he did so could only result from lack of clarity on the Examiners part. That, in fact is the point of the enablement rejection. Applicants' own specification says as much in lines 7-27, page 27. Firstly, the factual conclusion of undue experimentation is a logical result of the analysis of the facts presented above. Assertions do not change the facts. Even though the textbooks were published 3 years prior to Applicants' filing date, there is no evidence presented that the situation has changed in that three years. Secondly, the declaration is discussed above. Thirdly, merely alleging that the references and the facts presented are not persuasive is not evidence.

12. Claims 1-3, 7, 9-18, 20-46, 48-53, 150-153, 155-157, 165, 166, and 171-173 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase in lines 21-22, page 13 "M is not -NH(lower alkyl), -N(lower alkyl)$_2$" is indefinite. M-PO_3^{-2} etc must be biologically active. Are $^{-2}O_3P$-NH(lower alkyl) or $^{-2}O_3P$-N(lower alkyl)$_2$ biologically active? If not, the proviso excluded something that is not present.

Applicants made no traverse of this rejection.

13. Claim 150 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 150 provides for transforming "a compound drug having a $-PO_3^{2-}$ ...", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. All the word "transforming" does is delineate which molecules are staring materials and which are products. No reactions are named. No reagents are named. No conditions essential for any successful chemical reaction are specified. What chemical reactions are being claimed?

The Examiner suggests adding the reagents and condition they intend to use to the claims.

Claim 150 remains rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153

USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Applicants point to a Mitsunobo reaction on page 94 and Examples 1 and 4 as defining their synthetic process. They argue that these reagents and conditions are the steps required by 35 U.S.C. 101. This is not persuasive. The claims measure the invention. The U.S. Court of Customs and Patent Appeals wrote *In re Priest*, 199 USPQ 11 "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim." *In re Prater*, 56 CCPA 1381, 1396, 415 F.2d 1393, 1405, 162 USPQ 541, 551 (1969)." The steps of a chemical process are the reagents and reactions required to affect the claim transformation. All Applicants have done is label what is the starting material and what is the product. No chemical steps are to be found in the claim.

14. Claims 155-157 and 166 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "oxidizing agent" is indefinite. Pauling's "General Chemistry" on page 248 says, "[a]n atom, molecule, or ion which takes up electrons is called an oxidizing agent". "The Condensed Chemical Dictionary" defines "oxidizing material" as "any

compound that spontaneously evolves oxygen..". What are the structures of the oxidizing agents, whose use Applicants claim? The Examiner suggests using lines 16-18, page 93 to list the "oxidizing agents" intended.

Applicants argue that functional language is not improper and has been found acceptable *In re Barr*, 444 F.2d 588, 170 USPQ 33 (CCPA 1971). This is not persuasive because the claim lacks the definite boundaries on the patent protection sought required by *In re Barr*. Beyond the examples in the specification we do not know the structure of this chemical reagent, just the function it must serve.

Conclusion

15. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The FAX number for before final amendments is (703) 872-9306. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, you can reach the Examiner's supervisor, Mukund Shah at (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.

Thomas McKenzie, Ph.D.
Patent Examiner
Art Unit 1624

TCMcK
June 13, 2003